



# REGULATORY GUIDE 7.2



## EXAMPLES OF SEVERITY LEVELS OF VIOLATIONS FOR LICENSEES, REGISTRANTS, AND CERTIFIED INDUSTRIAL RADIOGRAPHERS

This guide contains examples of severity levels of violations for non-compliance with rules in accordance with 25 Texas Administrative Code, Chapter 289. The examples of severity levels of violations are for licensees, registrants, and certified industrial radiographers as stated in §289.205(k), "Hearing and Enforcement Procedures" and §289.232(k)(2)(E), "Radiation Control Regulations for Dental Radiation Machines."

The following examples of severity levels reflect only the seriousness of the violation and are not exhaustive. Nor are they controlling, since severity levels may be elevated or reduced in accordance with the criteria in §289.205(k)(3) and §289.232(k)(2)(E)(ii).

Criteria for elevating violations to a higher severity level include the following:

- more than one violation resulted from the same underlying cause
- a violation contributed to or was the consequence of the underlying cause, such as a management breakdown or breakdown in the control of licensed or registered activities
- a violation occurred multiple times between inspections
- a violation was willful. This means the violation was the result of careless regard for requirements, deception, or other indications of willfulness by the licensee/registrant or employees of the licensee/registrant, or certified industrial radiographer
- compliance history

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Regulatory Guides are issued to describe and make available acceptable methods of implementing specific sections of **Title 25 Texas Administrative Code Chapter 289, Texas Regulations for Control of Radiation**, to delineate techniques used by the staff in evaluating specific issues, or to provide guidance to applicants, licensees, or registrants. Regulatory Guides are **NOT** substitutes for regulations and compliance with them is not required. Methods and solutions different from those set out in the guides will be acceptable if they provide a basis for the Texas Department of Health, Bureau of Radiation Control, to make necessary determinations to issue or continue a license or certificate of registration.

Comments and suggestions for improvements in these Regulatory Guides are encouraged at all times and they will be revised, as appropriate, to accommodate comments and to reflect new information or experience. Comments should be sent to the Deputy Director, Standards and Industrial Radiographer Certification, Bureau of Radiation Control, Texas Department of Health, 1100 W. 49th Street, Austin, Texas 78756-3189.

Regulatory guides may be reproduced or may be obtained by contacting the agency at (512) 834-6688 or accessing the Bureau of Radiation Control web page at [www.tdh.state.tx.us/ech/rad/pages/brc.htm](http://www.tdh.state.tx.us/ech/rad/pages/brc.htm)

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Criteria for reducing violations to a lower level include the following:

- the licensee or registrant identified and corrected the violation prior to the agency inspection
- the licensee's or registrant's actions corrected the violation and prevented recurrence

Examples of severity levels are divided into the following sections.

- I. Severity levels of violations for all licensees, registrants, and certified industrial radiographers.....page 7.2 - 3
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Questions concerning severity levels and violations may be directed to the following programs at 512-834-6688.

- radioactive materials compliance and inspection
- x-ray compliance and inspection
- mammography compliance and inspection

I. Severity levels of violations for all licensees, registrants, and certified industrial radiographers.

A. Severity level I violations are violations that are most significant and may have a significant negative impact on occupational and/or public health and safety or on the environment.

1. Exposure to a worker in excess of 25 rems of radiation to the whole body, or 250 rems to the skin of the whole body, or 75 rems to the lens of the eye.

- dental registrants [§289.232(i)(4)(A)]
- licensees [§289.202(f)]
- registrants [§289.231(m)]

2. Annual whole-body exposure in excess of 5 rems of radiation to a member of the public or to a radiation worker who is a minor.

Dose to a member of the public

- dental registrants [§289.232(i)(4)(B)]
- licensees [§289.202(n)]
- registrants [§289.231(o)]

Dose to minors

- dental registrants [§289.232(i)(4)(A)(i)(III)]
- licensees [§289.202(l)]
- registrants [§289.231(m)(1)(C)]

3. Radiation levels, contamination levels, or releases to restricted or unrestricted areas that exceed ten times any limit specified in the rules.

- dental registrants [§289.232(j)(2)(B)(i) and (ii)]
- licensees [§289.202(xx)(1) and (2), (ggg)(2)(C), and (ggg)(6)-(8)]
- registrants [§289.231(hh)(1) and (2), (ii)(1)(C)]

4. Exposure of a worker in a restricted area(s) to ten times the regulatory limits specified in rule.

- dental registrants [§289.232(i)(4)(A)]
- licensees [§289.202(f), (l), and (m)]
- registrants [§289.231(m)]

5. A required system or equipment designed to prevent or mitigate a serious safety event or unnecessary exposure is absent or inoperable due to a deliberate act by the licensee or registrant (e.g., bypassing an interlock when an individual could receive an external exposure greater than the annual limit).
  - accelerators used in research and development [§289.229(f)(3)(A) and §289.231(t)-(v)]
  - industrial radiography [§289.202(s), (t), and (y) and §289.255(r) and (v)(2)]
  - licensees [§289.202(s)-(y)]
  - medical use of radioactive material [§289.256(dd)(5), and (10)-(13)]
  - radiation therapy [§289.229(h)(2)(A)(i)-(iv) and (vii), (h)(2)(C), (h)(3)(A), (B)(vi)-(vii) and §289.231(t)-(v)]
6. A material false statement by the licensee or registrant representative.
  - dental registrants [§289.232(k)(2)(C)(iii)]
  - licensees [§289.252(dd)(2)(A)]
  - registrants [§289.226(u)(2)(A)]
7. Activities involving radioactive material or a radiation machine that is specifically prohibited by either the rules or a license or certificate of registration condition.
  - dental registrants [§289.232(i)(2)]
  - mammography [§289.230(d)]
  - radiation therapy [§289.229(c)]
  - registrants [§289.226(c), §289.227(c), and §289.231(e)]
  - well logging and tracer studies [§289.253(d)]
8. Action taken by management to discriminate against an employee for communicating with or attempting to communicate with the agency to report violations or request an inspection, etc.
  - dental registrants [§289.232(k)(1)(N)]
  - licensees and registrants [§289.203(g)(3)]

9. Deliberate exposure of an individual to radiation or radioactive materials except by or under the supervision of an individual licensed to engage in the healing arts.

- dental registrants [§289.232(i)(2)(B)]
- licensees [§289.202(b)(1)]
- registrants [§289.231(b)(1)]

10. Refusing authorized agency personnel access to facilities and/or equipment during normal working hours for the purpose of conducting compliance inspections or investigations.

- dental registrants [§289.232(k)(1)]
- licensees [§289.201(e)]
- registrants [§289.231(kk)]

B. Severity level II violations are violations that are very significant and may have a negative impact on occupational and/or public health and safety or on the environment.

1. A single exposure to a worker in excess of 5 rems of radiation to the whole body, 50 rems to the skin of the whole body, or 15 rems to the lens of the eye.

- dental registrants [§289.232(i)(4)(A)]
- licensees [§289.202(f)]
- registrants [§289.231(m)]

2. Annual exposure above 500 millirem (mrem) to a member of the public or to a radiation worker who is a minor.

Dose to a member of the public

- dental registrants [§289.232(i)(4)(B)]
- licensees [§289.202(n)]
- registrants [§289.231(o)]

Dose to minors

- dental registrants [§289.232(i)(4)(A)(i)(III)]
- licensees [§289.202(l)]
- registrants [§289.231(m)(1)(C)]

3. Radiation levels, contamination levels, or releases to restricted or unrestricted areas that exceed five times any limit specified in the rules.
    - dental registrants [§289.232(j)(2)(B)(i) and (ii)]
    - licensees [§289.202(xx)(1) and (2), (ggg)(2)(C), and (ggg)(6)-(8)]
    - registrants [§289.231(hh)(1) and (2), (ii)(1)(C)]
  4. A required system or equipment, designed to prevent or mitigate a serious safety event or unnecessary exposure, is absent or inoperable.
    - accelerators used in research and development [§289.229(f)(3)(A) and §289.231(t)-(v)]
    - industrial radiography [§289.255(r) and (v)(2)]
    - licensees [§289.202(s)-(y)]
    - radiation therapy [§289.229(h)(2)(A)(i)-(iv), and (vii), (h)(2)(C), and (h)(3)(A), (B)(vi)-(vii) and §289.231(t)-(v)]
    - registrants [§289.231(t)-(v)]
    - teletherapy, remote controlled brachytherapy units, gamma stereotactic radiosurgery units [§289.256(dd)(5) and (10)-(13)]
  5. Refusing authorized personnel access to regulatory records during a compliance inspection or investigation after being provided with reasonable notification (24 hours) of the agency's intent to inspect.
    - dental registrants [§289.232(k)(1)]
    - licensees [§289.201(e)]
    - registrants [§289.231(kk)]
  6. Failure to restrict access to any high or very high radiation area.
    - licensees [§289.202(s)-(u)]
    - registrants [§289.231(t) and (u)]
- C. Severity level III violations are violations that are significant and, if not corrected, could threaten occupational and/or public health and safety or the environment.
1. Radiation levels in an unrestricted area such that an individual could receive greater than 100 mrem in a one-hour period.

- dental registrants [§289.232(i)(4)(B)(i)(II)]
  - licensees [§289.202(n)(1)(B)]
  - registrants [§289.231(o)(1)(B)]
2. Failure to notify the agency immediately of an event involving a source of radiation that may have caused or threatened to cause excessive exposures.
- dental registrants [§289.232(j)(2)(B)]
  - licensees [§289.202(xx)(1)]
  - registrants [§289.231(hh)(1)]
3. Failure to notify the agency within 24 hours of discovery of loss of control of a source of radiation that may have caused or threatened to cause exposures exceeding the limits.
- dental registrants [§289.232(j)(2)(B)(ii)]
  - licensees [§289.202(xx)(2) and (7)]
  - registrants [§289.231(hh)(2)]
4. Failure to notify the agency immediately following the filing of a voluntary or involuntary petition for bankruptcy.
- dental registrants [§289.232(h)(5)(C)]
  - licensees [§289.252(x)(4)-(6)]
  - registrants [§289.226(p)(5)]
5. Use of radioactive material or an x-ray machine for a purpose or activity that is not specifically authorized by the license or certificate of registration.
- dental registrants [§289.232(h)(4)(E)]
  - licensees [§289.252(x)(3)]
  - registrants [§289.226(p)(7)]
6. Failure to secure radiation machines or radioactive material from unauthorized removal or access by any member of the public.
- dental registrants [§289.232(i)(6)(O)]
  - licensees [§289.202(y)(1)]
  - registrants [§289.231(v)(1)]



7. Failure to obtain reciprocal recognition of a non-Texas authorization prior to performing any activity in Texas that would require a specific license or certificate of registration.

- dental registrants [§289.232(h)(9)]
- industrial radiographers [§289.255(l)(2)]
- licensees [§289.252(ee)]
- registrants [§289.226(v)]

- D. Severity level IV violations are violations that are of more than minor significance, but if left uncorrected, could lead to more serious circumstances.

1. A radiation level in an unrestricted area such that an individual could receive greater than two mrem in any one-hour period.

- dental registrants [§289.232(i)(4)(B)(i)(II)]
- licensees [§289.202(n)(1)(B)]
- registrants [§289.231(o)(1)(B)]

2. Failure to notify the agency no less than three working days prior to performing any operation in this state that requires reciprocal recognition.

- dental registrants [§289.232(h)(9)(C)]
- licensees [§289.252(ee)(1)(B)]
- registrants [§289.226(v)(3)]

3. Failure to appropriately post areas as radiation area, high radiation area, and/or very high radiation area.

- dental registrants [§289.232(i)(5)(D)]
- licensees [§289.202(aa)]
- registrants [§289.231(x)]

4. Failure to provide general training and instructions to workers.

- dental registrants [§289.232(i)(4)(D)]
- licensees and registrants [§289.203(c)]

5. Failure of the radiation safety officer (RSO) to perform the duties of RSO as listed in the following:

- dental facilities [§289.232(h)(11)]
- healing arts, radiation therapy, and veterinary facilities [§289.226(s)(2)]
- industrial radiography [§289.255(m)(4)(C)]
- industrial use of radioactive material [§289.252(f)(3) and (4)]
- medical and veterinary use of radioactive material [§289.256(g)(1)(B)(C)]
- well logging and tracer studies [§289.253(r)(3)]

6. Failure to maintain records at authorized use locations as required by the rules or license or certificate of registration condition.

- bone densitometer registrants [§289.227(g)(11) and (12)]
- dental registrants [§289.232(k)(1)(X)(i)]
- healing arts and veterinary registrants [§289.227(t)]
- industrial radiography licensees and registrants [§289.255(w) and (y)(3)]
- irradiator licensees [§289.258(cc)]
- licensees using well logging and tracer studies [§289.253(z) and (bb)(5)]
- mammography registrants [§289.230(r)(1)-(3)]
- medical and veterinary use of radioactive material licensees [§289.256(n) and (ff)(2)]
- radiation therapy registrants [§289.229(k)]

7. Failure to submit a written report to an individual when required.

- licensees [§289.202(aaa)(2)]
- licensees and registrants [§289.203(d)(3)]

E. Severity level V violations are violations that are of minor safety or environmental significance.

1. Failure to maintain a current copy of all applicable sections of 25 TAC §289 as stated on the license or certificate of registration at each authorized use location.

- bone densitometer facilities [§289.227(g)(11) and (12), (t)(1)(A)]
  - dental facilities [§289.232(i)(5)(B)(i)(I)]
  - healing arts and veterinary facilities [§289.227(t)(1)(A)]
  - industrial radiography facilities [§289.255(w)(9)(A)(iii)]
  - mammography facilities [§289.230(r)(1)(D) and (r)(3)(I)]
  - medical and veterinary use of radioactive material facilities [§289.256(n) and (ff)(2)]
  - radiation therapy facilities [§289.229(h)(5)(A)(i)]
  - well logging and tracer study facilities [§289.253(z)(1) and (bb)(5)(O)]
2. Failure to post the “Notice to Employees” form (BRC Form 203-1 for licensees and registrants and BRC Form 232-1 for dental facilities).
- dental registrants [§289.232(i)(5)(C)]
  - licensees and registrants [§289.203(b)(3)]

- II. Additional severity levels of violations specifically related to the use of radioactive material.
- A. Severity level I violations are violations that are most significant and may have a significant negative impact on occupational and/or public health and safety or on the environment.
1. Release of radioactive material to an unrestricted area(s) in excess of ten times the limits specified in Table 2 of §289.202(ggg)(2)(F).
  2. Disposal of licensed material to a sanitary sewage system in quantities or concentrations that exceed ten times the limits specified in §289.202(gg).
  3. Possession of specifically-licensable quantities of radioactive material without having a valid license issued by this state, another agreement state, or the U.S. Nuclear Regulatory Commission [§289.252(a)-(c)].
- B. Severity level II violations are violations that are very significant and may have a negative impact on occupational and/or public health and safety or on the environment.
1. Release of radioactive material to an unrestricted area in excess of five times the limits specified in Table 2 of §289.202(ggg)(2)(F).
  2. Failure to immediately notify the agency of a very significant incident or event:
    - a. loss of control of a significant source of radiation [§289.202(ww)(1)(A)];
    - b. an excessive exposure to an individual as described in §289.202(xx)(1)(A);
    - c. release of radioactive material in the amount described in §289.202(xx)(1)(B);
    - d. a leaking source [§289.202(bbb)]; or
    - e. well logging source ruptured downhole [§289.253(aa)].

3. Unauthorized disposal of licensed material to a sanitary sewer in quantities or concentrations that exceed five times the limits [§289.202(gg)].
  4. An intake of soluble uranium in excess of 10 milligrams per week [§289.202(f)(6)].
  5. Use of licensable quantities of radioactive material at a location that is not authorized for such use [§289.252(x)(3)].
  6. Failure to obtain appropriate agency approval before relocating licensable quantities of radioactive material to a new storage or storage/use site [§289.252(x)(3)].
  7. Loss of control of licensed quantities of radioactive material [§289.202(y)].
  8. Failure to apply for a General License Acknowledgment (GLA) within 30 days following acquisition of a generally-licensed device [§289.251(k)(1)(C)].
  9. Release of equipment contaminated with radioactive material that causes an exposure to members of the public that exceeds limits [§289.202(n)].
- C. Severity level III violations are violations that are significant and , if not corrected, could threaten occupational and/or public health and safety or the environment.
1. Release of radioactive material to an unrestricted area that exceeds any limit specified in Table 2 of §289.202(ggg)(2)(F).
  2. Use of radioactive material for a purpose or activity that is not specifically authorized by the license [§289.252(x)(3)].
  3. Any unauthorized disposal of licensed material [§289.202(ff)-(ii)].
  4. Performance of regulated activities by an individual who is unauthorized, unqualified, or not designated on the license.
    - industrial radiography [§289.255(m)]
    - industrial use of radioactive material [§289.252(e)(1) and (f)(1)]

- medical and veterinary use of radioactive material [§289.256(b)(2)(B) and (f)(3)(B)]
  - well logging and tracer studies [§289.253(n)]
5. Any noncompliance with posting, labeling, marking, placarding, shipping papers, packaging, loading, or other transporting requirements in §289.257 that could result in any of the following:
    - a. improper identification of the type, quantity, or form of material;
    - b. failure of the carrier or recipient to exercise adequate controls; or
    - c. substantial potential for personnel exposure or contamination or improper transfer of material.
  6. Possession and/or use of an unauthorized form or quantity of radioactive material by a licensee. Possession of a total isotope activity in excess of a license limit [§289.252(w)(1)].
  7. Failure to hospitalize patients who have sealed source implants or have been administered therapeutic quantities of radioactive material in accordance with §289.256(w).
  8. Any medical event [§289.256(ee)].
  9. Failure to test interlocks or audible/visible alarm systems within the required time intervals [§289.202(u)(2)(H) and (I), §289.255(j)].
  10. Failure to conduct and document radiation surveys required by the rules [§289.202(p)].
  11. Failure to ensure that sealed sources, exposure devices, and transport containers have all the required warning and informational labels.
    - industrial radiography [§289.255(v)(6)(A), (E)(i),(ii), and (v)]
    - well logging [§289.253(m)]
  12. Performing downhole well logging or tracer operations without having a written agreement that meets the requirements of §289.253(d)(1) or (2), as applicable.

- D. Severity level IV violations are violations that are of more than minor significance, but if left uncorrected, could lead to more serious circumstances.
1. Failure to provide a written report to the agency within 30 days of the following:
    - a. loss of control of a significant source of radiation [§289.202(ww)(2)];
    - b. an excessive exposure to an individual as described in §289.202(xx)(8)(B);
    - c. release of radioactive material in the amount described in §289.202(yy);
    - d. well logging source ruptured downhole [§289.253(aa)(2)]; or
    - e. planned special exposures [§289.202(zz)].
  2. Failure to provide information to the agency within 30 days of lost, stolen, or missing licensed radioactive material in an aggregate quantity greater than 10 times the quantity specified in §289.202(ggg)(3) that is still missing [§289.202(ww)(1)(B)].
  3. Failure to submit a written report within five days of a leaking source [§289.202(bbb)].
  4. Failure to notify the agency, in writing, at least 30 days prior to either vacating an authorized storage location or premises where the licensee has possessed radioactive material [§289.202(ccc)].
  5. Failure to request termination of a license in a timely fashion or to notify the agency of an intent to cease all operations involving radioactive material [§289.252(y)(1)-(3)].
  6. Failure to conduct required leakage/contamination tests of sealed sources within the required time interval [§289.201(g)(1)].
  7. Failure to properly calibrate survey instruments if such device is used to perform a required survey; or other required radiation monitoring equipment within the specified time intervals [§289.202(p)(2) and (3)].

8. Failure to calibrate dose calibrators within the specified time intervals [§289.256(q)].
9. Implementing a substantive change in the approved operating, safety, and emergency procedures without prior approval from the agency [§289.256(m)(2)(G)].
10. Failure to develop, document, and implement an adequate Radiation Protection Program (RPP) [§289.202(e)].
11. Failure to ensure that radioactive material source holders and licensed radioactive material are legibly labeled with all required general information regarding the source or device [§289.202(cc) and §289.252(j)(3), (o)(2), and (r)(1)(C)].
12. Failure to maintain records [§289.202(ll)-(bbb)].
13. Failure to perform surveys of radiation levels in unrestricted areas to demonstrate compliance with the dose limits [§289.202(o)(1)].
14. Failure to maintain copies of approved operating, safety, and emergency procedures at authorized use locations.
  - industrial radiography [§289.255(w)(9)(A)(ii)]
  - irradiators [§289.258(t) and (cc)(4)]
  - medical use of radioactive material [§289.256(f)(3)(A)]
  - well logging and tracer studies [§289.253(p)]
15. Failure to post or post by reference the location of applicable rules, license, operating, safety, and emergency procedures, any notice of violations, and/or orders issued by the agency [§289.203(b)].



III. Additional severity levels of violations specifically related to the use of radiation machines.

A. Severity level I violations are violations that are most significant and may have a significant negative impact on occupational and/or public health and safety or on the environment.

1. Imaging a patient using a radiation machine that exceeds twice the entrance exposure limits.
  - dental registrants [§289.232(i)(6)(N)]
  - healing arts registrants [§289.227(k), Table I]
2. Using a fluoroscopy machine that is equipped with a non-image-intensified system [§289.227(c)(3)].
3. Failure to supply protective devices to individuals in the fluoroscopy room during fluoroscopic and/or spot film procedures [§289.227(o)(8)(B)].
4. Performing treatment using a radiation therapy machine after all of the viewing systems for the machine have failed [§289.229(h)(2)(B)(ii)(II) and (h)(3)(B)(iv)(II)].
5. Using a radiation therapy system for treatment without having a current calibration [§289.229(h)(2)(D)(ii) and (h)(3)(C)(ii)].
6. An individual other than a patient being in the treatment room during radiation therapy treatment [§289.229(h)(2)(D)(iv)(IV) and (h)(3)(C)(v)(I)].
7. Irradiation of an individual with a radiation therapy system that had previously failed to terminate an exposure at a preselected number of dose monitoring units without having necessary repairs made to the radiation therapy system [§289.229 (h)(3)(A)(vii)].
8. Irradiation of an individual without having to make positive selection of the energy and type of treatment beam from the treatment control panel [§289.229(h)(3)(A)(vi) and (xiii)(I)].

- B. Severity level II violations are violations that are very significant and may have a negative impact on occupational and/or public health and safety or on the environment.
1. Using radiation machines or providing services without applying for or being registered as required by the regulations.
    - dental registrants [§289.232(a)(2) and (h)(1)(A)]
    - registrants [§289.226(a) and (f)-(m)]
  2. Imaging a patient with a radiation machine that exceeds, by less than twice, the entrance exposure limits.
    - dental registrants [§289.232(i)(6)(N)]
    - healing arts registrants [§289.227(k), Table I]
  3. Holding the tube housing on radiation machines that are not designed to be hand-held during exposures [§289.227(i)(11) and (n)(7)].
  4. Using a fluoroscopy machine that exceeds the entrance exposure rates as specified in §289.227(o).
  5. Using a fluoroscopy machine that exceeds the primary barrier requirements as specified in §289.227(o)(1)(A) and (B).
  6. Failure to have current fluoroscopy dose measurements performed by a licensed medical physicist with a speciality in diagnostic radiological physics [§289.227(o)(3)(D)].
  7. Using radiation therapy systems with beam limiting devices that do not meet the requirements [§289.229(h)(2)(A)(iii)].
  8. Failure of a radiation therapy system control panel to have positive indication of the parameters of the beam or indicate when the beam is on [§289.229(h)(2)(A)(ix)].
  9. Interlocks for the entrance door and/or interior booths for radiation therapy are inoperative or not present [§289.229(h)(2)(C)(iii) and (h)(3)(A)(xvii) and (B)(vii)].
  10. Interlocks for the entrance door and/or interior booths for accelerators used in research and development are inoperative or not present [§289.229(f)(3)].

11. Failure to perform calibration of a radiation therapy unit annually or after change or repair of components that could affect the radiation output [§289.229(h)(2)(D)(ii)(I) and (h)(3)(C)(ii)(I)].
  12. Failure to immediately notify the agency of the following:
    - a. a stolen, lost, or missing radiation machine; or
      - dental registrants [§289.232(j)(2)(A)]
      - registrants [§289.231(gg)]
    - b. an excessive exposure to an individual as described in the following:
      - dental registrants [§289.232(j)(2)(B)]
      - registrants [§289.231(hh)(1)]
  13. Use of a radiation machine at a location that is not authorized for such use.
    - dental registrants [§289.232(h)(4)(C)]
    - registrants [§289.226(o)(3)]
- C. Severity level III violations are violations that are significant and, if not corrected, could threaten occupational and/or public health and safety or the environment.
1. Failure to have and implement an adequate technique chart for diagnostic radiation machines.
    - dental registrants [§289.232(i)(6)(A)]
    - healing arts registrants [§289.227(i)(1)]
    - mammography registrants [§289.230(s)(3)]
    - radiation therapy simulator registrants [§289.229(h)(4)(A)(I)]
  2. Failure to perform a complete equipment performance evaluation at the required intervals.
    - dental registrants [§289.232(i)(7)(A)]
    - healing arts registrants [§289.227(q)(1)]

3. Failure to initiate corrective actions within 30 days after determination of any machine-related items of non-compliance discovered during the equipment performance evaluation.
  - dental registrants [§289.232(i)(7)(C)]
  - healing arts registrants [§289.227(q)(3)]
4. Use of diagnostic equipment with inadequate filtration.
  - dental registrants [§289.232(i)(6)(F)]
  - healing arts registrants [§289.227(k)(5)]
5. Use of diagnostic equipment that does not meet the requirements of the following as related to beam limiting devices or source to image distance.
  - dental registrants [§289.232(i)(6)(M) and (i)(12)]
  - healing arts registrants [§289.227(m)(1)]
  - radiation therapy simulator registrants [§289.229(h)(4)(B)(iii)]
  - veterinary registrants [§289.227(n)(2)]
6. Using a radiation machine with a timer that does not comply with the requirements in the following subsections:
  - dental registrants [§289.232(i)(6)(I)]
  - healing arts registrants [§289.227(m)(2)(B)]
  - radiation therapy simulator registrants [§289.229(h)(4)(B)(iv)]
  - veterinary registrants [§289.227(n)(4)]
7. The output of diagnostic radiation machines is not linear or reproducible.
  - dental registrants [§289.232(i)(6)(J)]
  - healing arts registrants [§289.227(m)(4) and (5)]
  - radiation therapy simulator registrants [§289.229(h)(4)(B)(vii) and (viii)]
8. Use of a fluoroscopy machine that fails to limit the source to skin distances as required by §289.227(o)(6).
9. Failure to develop a maintenance schedule for a computerized tomographic (CT) machine [§289.227(p)(4)].

10. Failure to stop treatment if the primary and backup viewing system for the CT machine fails.
    - radiation therapy CT simulator registrants [§289.229(h)(4)(D)(ii)(I)(-b-)]
    - registrants with CT machines [§289.227(p)(2)(B)(ii)]
  11. Failure to have continuous observation of a patient during CT procedures [§289.227(p)(2)(B)].
  12. Failure of a radiation therapy system over 1 MeV to have an interlock to prevent irradiation if the proper filter is not in place. [§289.229(h)(3)(A)(ii)(I) and (IV)]
  13. Failure to have a preset timer visible at the control panel of a radiation therapy system over 1 MeV [§289.229(h)(3)(A)(xi)].
  14. Failure to have a locking device at the control panel of a therapy system to prevent unauthorized use of the system [§289.229(h)(2)(A)(ix)(V) and (h)(3)(A)(viii)].
  15. Performance of regulated activities by an individual who is unauthorized, unqualified, or not designated on the certificate of registration.
    - dental registrants [§289.232(h)(1)(C)-(E)]
    - registrants [§289.226(e)(2), (f)(4), (6) and (7), and (w)(1)]
  16. Use of an unregistered radiation machine for more than 30 days without obtaining or applying for a certificate of registration.
    - dental registrants [§289.232(a)(2) and (h)(1)(A)]
    - registrants [§289.226(a) and (f)-(m)]
  17. Failure to test interlocks or audible/visible alarm systems within the required time intervals for accelerators used in research and development [§289.229(f)(3)(A)(viii)].
- D. Severity level IV violations are violations that are of more than minor significance, but if left uncorrected, could lead to more serious circumstances.

1. Engaging a provider of radiation machine services who is not registered or authorized by the agency to provide such services [§289.226(p)(3)].
2. Failure of the registrant to notify the agency of changes to the certificate of registration.
  - dental registrants [§289.232(h)(5)(A)]
  - registrants [§289.226(p)(1) and (2)]
3. Failure to test protective aprons, gloves, and/or shields for defects annually [§289.227(i)(4)].
4. Failure to perform surveys of radiation levels in unrestricted areas to demonstrate compliance with the dose limits [§289.231(p)(1)].
5. Failure to maintain dose measurement records for CT machines for inspection [§289.227(p)(3)(C)].
6. Failure to include the required information on the maintenance schedule for CT machines [§289.227(p)(4)].
7. Failure to maintain phantom images for CT quality control [§289.227(p)(4)(B)].
8. Failure to have available a copy of the most recent x-ray calibration for a radiation therapy system at a designated place in the facility [§289.229(h)(2)(D)(ii)(VI) and (h)(3)(C)(ii)(VI)].
9. Failure to maintain a copy of the most recent spot check for a radiation therapy system at a designated place in the facility [§289.229(h)(2)(D)(iii)(VI) and (h)(3)(C)(iii)(VI)].
10. Failure to retain records or include all information as required concerning radiation therapy events (misadministrations) [§289.229(j)].
11. Failure to provide a written report to the agency within 30 days of the following:
  - a. a stolen, lost, or missing radiation machine; or
    - dental registrants [§289.232(j)(2)(A)(ii)]

- registrants [§289.231(gg)]
- b. an excessive exposure to an individual as described in the following:
- dental registrants [§289.232(j)(2)(C)(i)]
  - registrants [§289.231(ii)(1)(B)]
12. Failure to maintain copies of approved operating and emergency procedures at authorized use locations.
- dental registrants [§289.232(i)(3)]
  - healing arts and veterinary registrants [§289.227(i)(2)]
  - radiation therapy registrants [§289.229(h)(1)(D)]
- E. Severity level V violations are violations that are of minor safety or environmental significance.
1. Failure to maintain records of receipt, transfer, disposal, surveys, calibrations, maintenance, or equipment performance evaluation tests, as applicable.
- bone densitometer registrants [§289.227(g)(11) and (12)]
  - dental registrants [§289.232(k)(1)(X)(i)]
  - healing arts and veterinary registrants [§289.227(t)]
  - mammography registrants [§289.230(r)]
  - radiation therapy registrants [§289.229(k)]
2. Failure to post developer temperature for automatic processors or time-temperature chart for manual processors.
- dental registrants [§289.232(i)(14)(A)]
  - healing arts and veterinary registrants [§289.227(r)(1)]
  - radiation therapy simulator registrants [§289.229(h)(4)(A)(viii)(i)]
3. Failure to maintain records of darkroom light leak corrections or repairs.
- dental registrants [§289.232(i)(14)(F)]
  - healing arts and veterinary registrants [§289.227(r)(5) and (6)]
  - radiation therapy simulator registrants [§289.229(h)(4)(A)(viii)(V) and (VI)]

4. Failure to maintain documentation of chemical replacement for processors.
  - dental registrants [§289.232(i)(14)(F)]
  - healing arts and veterinary registrants [§289.227(r)(5) and (6)]
  - radiation therapy simulator registrants [§289.229(h)(4)(A)(viii)(V) and (VI)]
5. Failure to follow the film manufacturer's specifications for alternative film processing systems.
  - dental registrants [§289.232(i)(15)]
  - healing arts and veterinary registrants [§289.227(s)]
  - radiation therapy simulator registrants [§289.229(h)(4)(A)(ix)]
6. Failure to maintain calibration records for radiation therapy systems [§289.229(h)(3)(C)(ii)(IV) and (k)].
7. Failure to maintain dose monitor system calibration records for radiation therapy systems for three years after completion of the system's full calibration [§289.229(h)(3)(C)(ii)(IV) and (k)].
8. Failure to post or post by reference the location of applicable rules, certificate of registration, operating and safety procedures, any notice of violations, and/or orders issued by the agency.
  - dental registrants [§289.232(i)(5)(B)]
  - registrants [§289.203(b)]



IV. Severity levels of violations specifically related to mammography.

- A. Severity level I violations are violations that are most significant and may have a significant negative impact on occupational and/or public health and safety or on the environment.
1. Using a radiation machine not designed exclusively for mammography [§289.230(g)(1)].
  2. Using a mammographic machine for 12 months while not being accredited [§289.230(dd)(1)].
  3. Performing mammography with a mean glandular dose greater than 3.5 mGy [§289.230(l)(5)(F)].
  4. Failure to perform processor performance evaluation 30% of the days in one month that mammography was performed [§289.230(l)(1)].
  5. Failure to perform processor performance evaluation on four or more consecutive days that mammography was performed [§289.230(l)(1)].
  6. Processing mammography images with a processor that is operating out of limits four or more consecutive days [§289.230(l)(1)(A)].
  7. Failure to perform image quality evaluation for four or more weeks in any 12 consecutive week period [§289.230(l)(2)].
  8. Failure to have a medical physicist's survey performed for 24 months [§289.230(k)(1)(C)].
  9. Allowing a physician who does not meet the initial requirements and who is not licensed by the Texas State Board of Medical Examiners, to interpret mammograms [§289.230(f)(1) and (f)(1)(A)].
  10. Allowing a physician who is not certified by a United States Food and Drug Administration (FDA) approved body nor meets the alternative training requirements to interpret mammograms [§289.230(f)(1)(A)].
  11. Allowing a medical radiologic technologist who has not obtained the required initial formal education in mammography to perform mammography [§289.230(f)(2)(A)].

12. Allowing a person who does not meet the initial requirements and has not obtained a license under the Texas Medical Physics Practice Act to conduct a physicist's survey [§289.230(f)(3) and (f)(3)(A)].
  13. Failure to have an adequate system to communicate examination results to patients or health care providers [§289.230(i)(2)].
  14. Performing mammographic examinations while the phantom image score is:
    - a. less than 3 fibrils;
    - b. less than 2 speck groups; or
    - c. less than 2 masses [§289.230(l)(2)(C)(i) and (nn)(5)].
- B. Severity level II violations are violations that are very significant and may have a negative impact on occupational and/or public health and safety or on the environment.
1. Using a mammographic unit that has only one image receptor size [§289.230(g)(3)(A)].
  2. Using a mammographic unit that doesn't have operable moving grids and compression paddles for each receptor size [§289.230(g)(3)(B)].
  3. Performing mammography with a mean glandular dose greater than 3.2 mGy but less than 3.5 mGy [§289.230(l)(5)(F)].
  4. Failure to have a post-exposure mAs display for automatic exposure control mode [§289.230(g)(8)(C)].
  5. Failure to perform a required mammography equipment evaluation [§289.230(l)(11)].
  6. Performing mammography with a non-accredited machine [§289.230(dd)(1)].
  7. Performing mammography while the phantom image score is:
    - a. fibril <4 but >3;
    - b. speck groups <3 but >2; or
    - c. masses <3 but >2 [§289.230(l)(2)(C)].

8. Performing mammography with a darkroom fog density  $\geq 0.10$  [§289.230(l)(4)(A)].
9. Failure to initiate a procedure for infection control or dealing with customer complaints [§289.230(l)(14) and (mm)].
10. Failure to perform processor performance evaluation more than 10% but less than 30% of the days in one month that mammography was performed [§289.230(l)(1)].
11. Failure to perform processor performance evaluation on two to four consecutive days in which mammography was performed [§289.230(l)(1)].
12. Processing mammographic films when the processor performance evaluation indicates the action limits were exceeded for two to four consecutive days [§289.230(l)(1)].
13. Failure to conduct image quality evaluation two or three weeks out of any 12 consecutive weeks [§289.230(l)(2)].
14. Failure to take corrective action before resuming mammography when any of the following test results exceed the action limits [§289.230(l)(9)]:
  - a. processor performance;
  - b. image quality evaluation;
  - c. darkroom fog;
  - d. screen/film contact;
  - e. compression device performance;
  - f. automatic exposure control (AEC) or AEC reproducibility;
  - g. focal spot condition;
  - h. breast entrance air kerma reproducibility; or
  - i. dosimetry.

15. Failure to expose the mammographic phantom at the clinical kilovolt peak (kVp) for the image quality evaluation [§289.230(l)(2)(C)].
16. Failure to verify satisfactory performance on a mobile system prior to performing mammography [§289.230(l)(8)].
17. Exceeding 12 months between physicist's surveys [§289.230(l)(10)].
18. Failure to identify on the written report the person who conducted the annual physicist survey or mammography equipment evaluation [§289.230(l)(10)(C)].
19. Omission of any of the following tests on the physicist's survey [§289.230(l)(10)]:
  - a. focal spot evaluation;
  - b. AEC performance;
  - c. AEC reproducibility;
  - d. AEC performance capability;
  - e. average glandular dose;
  - f. image quality evaluation with phantom;
  - g. artifact evaluation; or
  - h. technologist quality control (QC) test evaluation.
20. Employing any of the following who failed to complete any one of the initial training or experience requirements:
  - a. interpreting physician [§289.230(f)(1)(A)];
  - b. medical radiologic technologist [§289.230(f)(2)(A)]; or
  - c. licensed medical physicist [§289.230(f)(3)(A)].

21. Employing any of the following who failed to complete any one of the continuing education or experience requirements:
    - a. interpreting physician [§289.230(f)(1)(C)];
    - b. medical radiologic technologist [§289.230(f)(2)(C)]; or
    - c. licensed medical physicist [§289.230(f)(3)(C)].
  22. Failure to include final assessment categories or identification of the interpreting physician on the report of mammographic examination [§289.230(i)(1)].
  23. Failure to set up and perform an adequate mammography medical outcome audit [§289.230(m)].
  24. Failure to apply for and receive Texas certification for mammography [§289.230(t)(1)].
- C. Severity level III violations are violations that are significant and, if not corrected, could threaten occupational and/or public health and safety or the environment.
1. X-ray field to light field misalignment is greater than 2% of the SID [§289.230(l)(5)(G)(ii)].
  2. X-ray field to image receptor misalignment is greater than 2% of the SID [§289.230(l)(5)(G)(i)].
  3. Imaging the vertical edge of the compression paddle on the image receptor [§289.230(l)(5)(G)(iii)].
  4. Compression paddle to image receptor misalignment is greater than 1% of the SID [§289.230(l)(5)(G)(iii)].
  5. Exceeding the limits for the following:
    - a. exposure reproducibility coefficient of variation [§289.230(l)(5)(E)];
    - b. beam quality [§289.230(l)(5)(D)]; or
    - c. dark room fog [§289.230(l)(4)(A)].

6. Failure to include any of the following in the quality assurance (QA) program [§289.230(k)]:
  - a. identification of the QA personnel;
  - b. technique tables and charts;
  - c. written procedures for QC tests; or
  - d. written acceptable limits for each QC test.
7. Failure to conduct the following QC tests as required:
  - a. fixer retention [§289.230(l)(3)(A)];
  - b. compression device performance [§289.230(l)(4)(C)];
  - c. repeat analysis [§289.230(l)(3)(B)];
  - d. screen-film contact [§289.230(l)(4)(B)]; or
  - e. dark room fog [§289.230(l)(4)(A)].
8. Failure to have physicist's survey report available for review [§289.230(l)(10)(B)].
9. Failure to obtain the written physicist's survey report within 30 days of the survey [§289.230(l)(10)(B)].
10. Failure to initiate or complete corrective action when test results fall out of the established limits [§289.230(l)(9)].
11. Failure to include any of the following items/tests in the physicist's survey report [§289.230(l)(10)]:
  - a. pass/fail list;
  - b. recommendations for failed items;
  - c. adequate evaluation of technologist's QC tests;
  - d. adequate collimation evaluation;

- e. kVp accuracy;
  - f. kVp reproducibility;
  - g. beam quality measurement;
  - h. uniformity of screen speed (for all cassettes used);
  - i. radiation output; and
  - j. decompression.
- 12. Failure to provide documentation of qualifications for interpreting physicians, medical radiologic technologists, or licensed medical physicist [§289.230(f)(4)].
  - 13. Failure to notify the agency within 15 days of changes in approved self-referral mammography procedures [§289.230(w)(1)].
  - 14. Failure to include the required identifying information as specified in §289.230(i)(5) on mammograms.
- D. Severity level IV violations are violations that are of more than minor significance, but if left uncorrected, could lead to more serious circumstances.
- 1. Failure to notify the agency prior to any of the following [§289.230(w)(1)]:
    - a. disposal or transfer of a mammographic machine;
    - b. change of facility name;
    - c. change in street address where mammographic machine(s) will be used; or
    - d. change of mammographic machine(s).

2. Failure to notify the agency within 30 days of a change in one of the following [§289.230(w)(2)]:
    - a. radiation safety officer;
    - b. lead interpreting physician;
    - c. interpreting physician;
    - d. medical radiologic technologist; or
    - e. licensed medical physicist.
  3. Failure to maintain documentation of the Q C program for the required period of time [§289.230(k)(2)].
  4. Failure to maintain copies of approved operating and emergency procedures at authorized use locations [§289.230(s)(1)].
- E. Severity level V violations are violations that are of minor safety or environmental significance.
1. Failure to post or post by reference the location of applicable rules, certificate of registration, operating and safety procedures, any notice of violations, and/or orders issued by the agency [§289.203(b)].



V. Additional severity levels of violations specifically related to industrial radiographers.

Severity level III violations are violations that are significant and, if not corrected, could threaten occupational and/or public health and safety or the environment

A. Examples of severity levels for all industrial radiographers.

Failure of an industrial radiography worker to do the following:

- (1) possess a valid certification ID card from the agency or other certifying entity on his/her person [§289.255 (m)(2)(A)(iv) and (t)(2)];
- (2) possess a trainee status card or equivalent documentation [§289.255(m)(1)(B) and (t)(3)];
- (3) properly wear all required personnel monitoring equipment during radiographic operations [§289.255(q)(2) and (t)(4)];
- (4) “recharge” a pocket dosimeter at the beginning of the work shift [§289.255(q)(2)(D)];
- (5) possess an operable, calibrated survey instrument for each exposure device in use at the site [§289.255(t)(1)(A) and (4)];  
or
- (6) possess or properly utilize all required barrier ropes and warning signs when performing industrial radiography [§289.255(t)(1)(E) and (4)].

B. Examples of severity levels for industrial radiographers using sealed sources.

Failure of an industrial radiographer to do the following:

- (1) lock an exposure device, storage container, or source changer and remove the key after each exposure [§289.255(v)(2)];

- (2) have a proper operating team (two radiographers or a radiographer trainer and a trainee for each exposure device being used at the location) while performing field site radiography [§289.255(v)(7)(G)]; or
- (3) use, or correctly use, exposure-reduction devices as follows:
  - collimators [§289.255(v)(7)(H)]
  - handling tools or shielding [§289.255(v)(4)(D)].